

**Keywords:** written description, ranges

**General:** A disclosure of discrete values does not provide written description support for claimed ranges, a skilled artisan must be able to reasonably discern a disclosure of that range.

*Indivior UK Ltd. v. Dr. Reddy's Laboratories S.A.*  
United States Court of Appeals for the Federal Circuit  
No. 2020-2073  
Decided: November 24, 2021

## **I. Facts**

Dr. Reddy's Laboratories S.A. and Dr. Reddy's Laboratories, Inc. (collectively "DRL") petitioned for *inter partes* review of U.S. Patent No. 9,687,454 (the "'454 patent"), owned by Indivior UK Limited ("Indivior"). The '454 patent describes dissolvable films that include a therapeutic agent (e.g., to reduce dependency on narcotics). The '454 patent issued as the fifth continuation of U.S. Patent Application No. 12/537,571 (the "'571 application"), which was filed on August 7, 2009. DRL petitioned for *inter partes* review of claims 1–5 and 7–14.

DRL alleged that the polymer weight percentage limitations, added to the claims by amendment, do not have written description support in the '571 application as filed and, thus, are not entitled to the benefit of its filing date and that claims 1–5 and 7–14 were anticipated by U.S. Patent Publication 2011/0033541 ("Myers"), the February 10, 2011 publication of the '571 application. Indivior argued that the polymer weight percentage limitations were supported by the '571 application, that the claims were therefore entitled to the '571 application's priority date, and, thus, Myers was not prior art to the '454 patent. Indivior did not dispute that if the '571 application lacked written description of the claims and hence that Myers was deemed prior art, Myers would anticipate claims 1–5 and 7–14.

The United States Patent and Trademark Office Patent Trial and Appeal Board (the "Board") held that claims 1–5, 7, and 9–14 are unpatentable as anticipated and that DRL failed to demonstrate that claim 8 is anticipated. Indivior appealed the Board's decision regarding claims 1–5, 7, and 9–14 and DRL cross-appealed the Board's decision regarding claim 8.

## **II. Issues**

- (1) Did the Board err in finding that the '454 patent claims do not have written description support in the '571 application and that the claims are anticipated by Myers?

- (2) Did the Board err in holding that DRL failed to demonstrate that claim 8 is anticipated?

**III. Rule** – The test for adequate written description is whether the disclosure of the application relied upon reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date.

**IV. Holding and Reasoning**

- (1) No, the Board did not err. Claims 1–5, 7, and 9–14 are unpatentable as anticipated by Myers. Additionally, Indivior did not contest DRL’s anticipation arguments and the Board found that DRL showed that the claims are anticipated by Myers. The Federal Circuit affirmed the Board’s decision.

The Federal Circuit reviewed claims 1, 7, 8, and 12, as well as Table 1 and Table 5, of the ‘454 patent. *See* Appendix, pp. 3-4. Generally, these claims include polymer weight percentage limitations, which were at issue.

***Claim 1***

Regarding claim 1, the Court agreed with the Board that there is no written description support in the ‘571 application for the range of “about 40 wt % to about 60 wt %.” Specifically, the Court noted that the range was not expressly claimed in the ‘571 application. The Court further noted that the values of “40 wt %” and “60 wt %” are not stated in the ‘571 application. In affirming the Board’s decision, the Court noted that the specification must indicate with some clarity what the claim recites. In the case of a claimed range, a skilled artisan must be able to reasonably discern a disclosure of that range. No range of “about 40 wt % to about 60 wt %” appears in the application. Moreover, as other indications of polymeric content are present in the application, rendering it even less clear that an invention of “about 40 wt % to about 60 wt %” was contemplated as an aspect of the invention. The Court agreed with the Board’s analysis that the ‘571 application states, in the same paragraph, that one embodiment includes at least 25 wt %, which is out of range of the “about 40 wt % to about 60 wt %” and that an alternative embodiment includes “at least 50 wt %,” which is within the range but is not clear support in light of the other inconsistent language. The Court also noted that Table 1 and Table 5 do not describe the claimed ranges even though the listed polymer components may be added up to the “about 40 wt % to about 60 wt %” range. However, the values themselves do not constitute ranges since they are specific, particular examples. Moreover, the Court indicated that in this case, one must add up individual values, determine aggregate percentages, and then couple those aggregate percentages with other examples to create an otherwise unstated range.

***Claims 7 and 12***

Regarding claims 7 and 12, the Court also agreed with the Board for a similar reasoning with respect to claim 1. That is, there is no written description support for the claimed ranges based on individual wt % values in the specification. The Court emphasized that a “patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion.” *Brenner v. Manson*, 383 U.S. 519, 536 (1966). Additionally, Indivior did not contest that Myers would anticipate claims 1-5, 7, and 9-14 if Myers was deemed prior art. The Court affirmed the Board’s

decision that Indivior did not contest DRL's anticipation arguments, and found that DRL showed that claims 1-5, 7, and 9-14 were anticipated by Myers.

- (2) No, the Board did not err. Claims 1–5, 7, and 9–14 are unpatentable as anticipated by Myers. Additionally, Indivior did not contest DRL's anticipation arguments and the Board found that DRL showed that the claims are anticipated by Myers. The Federal Circuit affirmed the Board's decision.

### ***Claim 8***

Regarding claim 8, the Court agreed with the Board that the '571 application does include written description support for claim 8. The Board noted that DRL failed to demonstrate unpatentability of claim 8. In particular, the Board found that Table 1 and Table 5 in the '571 application disclosed formulations from which a polymer weight of 48.2%, as recited by claim 8, could be calculated by a person of ordinary skill in the art. The Court gave deference to the Board's fact-finding. Moreover, the Court noted that given claim 8 does not recite a range, but only a specific amount, which can be derived by selection and addition of the amounts of selected but identified components. The Court accepted that there is substantial evidence to support the Board's decision.

## **V. Appendix**

### **Claim 1**

What is claimed is:

1. An oral, self-supporting, A mucoadhesive film comprising:

- (a) about 40 wt % to about 60 wt % of a water-soluble polymeric matrix;
- (b) about 2 mg to about 16 mg of buprenorphine or a pharmaceutically acceptable salt thereof;
- (c) about 0.5 mg to about 4 mg of naloxone or a pharmaceutically acceptable salt thereof; and
- (d) an acidic buffer;

wherein the film is mucoadhesive to the sublingual mucosa or the buccal mucosa;

wherein the weight ratio of (b):(c) is about 4:1;

wherein the weight ratio of (d):(b) is from 2:1 to 1:5; and

wherein application of the film on the sublingual mucosa or the buccal mucosa results in differing absorption between buprenorphine and naloxone, with a buprenorphine  $C_{max}$  from about 0.624 ng/ml to about 5.638 ng/ml and a buprenorphine AUC from about 5.431 hr\*ng/ml to about 56.238 hr\*ng/ml; and a naloxone  $C_{max}$  from about 41.04 pg/ml to about 323.75 pg/ml and a naloxone AUC from about 102.88 hr\*pg/ml to about 812.00 hr\*ng/ml.

### **Claim 7**

7. The film of claim 1, wherein the film comprises about 48.2 wt % to about 58.6 wt % of the water soluble polymeric matrix.

Claim 8

8. The film of claim 7, wherein the film comprises about 48.2 wt % of the water soluble polymeric matrix.

Claim 12

12. The film of claim 1, wherein the weight ratio of (d):(b) is from about 1:1 to 1:5; wherein the weight ratio of (b):(a) is from about 1:3 to about 1:11.5; and wherein the film comprises about 48.2 wt % to about 58.6 wt % of the water soluble polymeric matrix.

Table 1 of '454

TABLE 1

Various Compositions of Film Dosages				
Components	Buprenorphine/Naloxone Films			
	Unit Formula (mg per film strip)			
Buprenorphine/Naloxone Ratios	16/4	12/3	8/2	2/0.5
<b>Active Components</b>				
Buprenorphine HCl	17.28	12.96	8.64	2.16
Naloxone HCl Dihydrate	4.88	3.66	2.44	0.61
<b>Inactive Components</b>				
Polyethylene Oxide, NF (MW 200,000)	27.09	20.32	13.55	—
Polyethylene Oxide, NF (MW 100,000)	12.04	9.03	6.02	19.06
Polyethylene Oxide, NF (MW 900,000)	4.82	3.62	2.41	2.05
Maltitol, NF	12.04	9.03	6.02	5.87
Flavor	6.0	4.5	3.0	2.4
Citric Acid, USP	5.92	4.44	2.96	2.96
HPMC	4.22	3.16	2.11	2.34
Ace-K	3.0	2.25	1.5	1.2
Sodium Citrate, anhydrous	2.68	2.01	1.34	1.34
Colorant	0.03	0.02	0.01	0.01
Total (mg)	100	75	50	40

Table 5 of '454

TABLE 5

Formulations of Test Films at Various pH Levels						
Component	Test formulation 1		Test formulation 2		Test formulation 3	
	% w/w	Mg/film	% w/w	Mg/film	% w/w	Mg/film
Buprenorphine HCl	21.61	8.64	17.28	8.64	17.28	8.64
Naloxone HCl Dihydrate	6.10	2.44	4.88	2.44	4.88	2.44